Express Mail Label No. **EV 337 198 905 US** Attorney Docket No. 54720-8015.US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:	
Bougueleret, et al.	EXAMINER: Unknown
SERIAL NO.: Not Yet Assigned	ART UNIT: Unknown
FILED: Filed Herewith	CONFIRMATION NO. Unknown
FOR: **ENGINEERED HUMAN KUNITZ-TYPE PROTEASE INHIBITOR**	

Information Disclosure Statement Accompanying Petition to Make Special

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The references listed on the enclosed Form PTO-1449 may be material to the examination of the above application. Copies of the references are submitted herewith. The Examiner is requested to make these references of official record in the present application. A detailed discussion of the most relevant prior art in view of the subject matter encompassed by the present claims is provided herewith.

EMBL Accession No. AL031663 provides a sequence encoding a Kunitz/Bovine pancreatic trypsin inhibitor.

This reference fails to show or suggest the sequences as specifically claimed in the instant invention. The Kunitz/Bovine pancreatic trypsin inhibitor domain is described on page 3. A comparison with the presently disclosed polypeptide sequences of SEQ ID NO: 1 and 2, show a substitution and a deletion at positions 64 and 73, respectively. More importantly, the sequence of AL031663 does not have at least 98% amino acid of SEQ ID NO: 1 or SEQ ID NO: 2 starting at position 75 of the AL031663 sequence, which is the sequence that would correspond to the novel Kunitz-type protease inhibitor domain.

EMBL Accession No. ABA09480 describes human proteins and DNA encoding sequences including an eppin-1 homologue encoding cDNA.

This reference fails to show or suggest the sequences as specifically claimed in the instant invention. A comparison with the nucleotide sequences shows that the nucleotide sequence of the present invention is not disclosed by ABA09480. Starting at position 363 of the ABA09480 sequence does not correspond to the presently disclosed sequence. This part of the ABA09480 sequence corresponds to the sequence encoding the novel Kunitz-type protease inhibitor domain of the present invention.

EMBL Accession No. ABB12236 and WO 01/57188 describes human proteins and DNA encoding sequences including an eppin-1 homologue encoding cDNA.

These references fail to show or suggest the sequences as specifically claimed in the instant invention. A comparison with the presently disclosed polypeptide sequences of SEQ ID NO: 1 and 2, show a substitution and a deletion at position 80. More importantly, the sequence of ABB12236 and WO 01/57188 does not have at least 98% amino acid of SEQ ID NO: 1 or SEQ ID NO: 2 starting at position 89 of the ABB12236 sequence, which is the sequence that would correspond to the novel Kunitz-type protease inhibitor domain.

EMBL Accession No. AF286370 and Richardson *et al.* (*Gene*, 270(1-2):93-102, 2001) describes a human eppin-3 (EPPIN) mRNA coding sequence.

These references fail to show or suggest the sequences as specifically claimed in the instant invention. As seen on page 2, the translation of the eppin-3 putative protease inhibitor sequence of AF286370 and Richardson et al. does not have at least 98% amino acid of SEQ ID NO: 1 or SEQ ID NO: 2, which is the sequence that would correspond to the novel Kunitz-type protease inhibitor domain.

EMBL Accession No. AF411861 and Clauss *et al.* (*Biochemical J.*, 368(1):233-242, 2002) describe a probable protease inhibitor WAP6 precursor mRNA from Homo sapiens.

These documents were published after the priority date claimed in the present invention and, thus, are not available as prior art under 35 U.S.C. § 102 or § 103.

EMBL Accession No. ABZ12026 and WO 02/070539 describe a human polynucleotide assembled from expressed sequence tags.

These references fail to show or suggest the sequences as specifically claimed in the instant invention. A comparison with the nucleotide sequences shows that the nucleotide sequence of the present invention is not disclosed by ABZ12026 and WO 02/070539. First, there is a substitution at position 332. More importantly, starting at position 363 of the ABZ12026 sequence does not correspond to the presently disclosed sequence. This part of the ABZ12026 sequence corresponds to the sequence encoding the novel Kunitz-type protease inhibitor domain of the present invention.

EMBL Accession No. APB69809 and WO 02/070539 describes a human polynucleotide assembled from expressed sequence tags.

These references fail to show or suggest the sequences as specifically claimed in the instant invention. A comparison with the presently disclosed polypeptide sequences of SEQ ID NO: 1 and 2, show a substitution at position 65. More importantly, the sequence of APB69809 and WO 02/070539 does not have at least 98% amino acid of SEQ ID NO: 1 or SEQ ID NO: 2 starting at position 75 of the APB69809 sequence, which is the sequence that would correspond to the novel Kunitz-type protease inhibitor domain.

No fees are believed due. However, should the Commissioner determine that fees are due in order for this Information Disclosure Statement to be considered, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2207.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,

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Date: March 22, 2001

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Form PTO-1449 (Modified) (Use several sheets if necessary)				COMPLETE IF KNOWN	
				Application Number	not yet assigned
				Confirmation Number	not yet assigned
				Filing Date	March 19, 2004
				First Named Inventor	Bougueleret et al.
				Group Art Unit	not yet assigned
				Examiner Name	not yet assigned
Sheet	1	of	1	Attorney Docket No.	54720-8015.US00

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	U.S. Patent or Application NUMBER	Kind Code (if known)	Name of Patentee or Inventor of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initial	Cite No.	Foreign Patent or Application Office	NUMBER	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear	T
		PCT	WO 01/57188	A2	Tang et al.	08/09/01		
		PCT	WO 02/070539	A2	Tang et al.	09/12/02		

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.	T
		Copy of International Search Report from PCT/EP03/01629 filed 18 February 2003.	
		EMBL Accession No. ABP69809, human polypeptide SEQ ID NO:1856, 2003.	
		EMBL Accession No. ABZ12026, human polynucleotide SEQ ID NO:908, 2003.	
		EMBL Accession No. AF411861, homo sapiens probable protease inhibitor WAP6 precursor, mRNA, complete cds., 2002.	
		EMBL Accession No. AF286370, homo sapiens eppin-3 (EPPIN) mRNA, complete cds, alternatively spliced, 2000.	
		EMBL Accession No. ABB12236, human eppin-1 homologue SEQ ID NO:2606, 2002.	
		EMBL Accession No. ABA09480, human eppin-1 homologue-encoding cDNA SEQ ID NO:1256, 2002.	
		EMBL Accession No. AL031663, human DNA sequence from clone RP3-461P17 on chromosome 20q12-13.2, 1998.	
		Richardson, R. T. *et al.*, "Cloning and sequencing of human *Eppin*: A novel family of protease inhibitors expressed in the epididymis and testis," *Gene* **370**, pp. 93-102, 2001.	
		Clauss, A. *et al.*, "A locus on human chromosome 20 contains several genes expressing protease inhibitor domains with homology to whey acidic protein," *Biochem. J.* **368**, pp. 233-242, 2002.	

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s).